IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS and SANOFI-AVENTIS U.S. LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. 07-572 (GMS)
ACTAVIS SOUTH ATLANTIC LLC, AUROBINDO PHARMA LTD., AURBINDO PHARMA USA INC., MYLAN PHARMACEUTICALS INC., PAR PHARMACEUTICAL, INC., RANBAXY INC., RANBAXY LABORATORIES LIMITED, SUN PHARMACEUTICAL INDUSTRIES, INC., SUN PHARMACEUTICAL INDUSTRIES LTD., TEVA PHARMACEUTICALS USA, INC., TORRENT PHARMA INC., and TORRENT PHARMACEUTICALS LIMITED,	)	
Defendants.	)	

ANSWER AND COUNTERCLAIMS OF DEFENDANTS
RANBAXY LABORATORIES LIMITED AND RANBAXY INC.

Defendants Ranbaxy Laboratories Limited and Ranbaxy, Inc. (collectively, "Ranbaxy"), hereby answer the Complaint of Plaintiffs Sanofi-Aventis and Sanofi-Aventis U.S. LLC (collectively, "Sanofi") as follows:

1. Ranbaxy lacks sufficient information to respond to the allegations of paragraph 1 of the Complaint and therefore denies those allegations.

2. Ranbaxy lacks sufficient information to respond to the allegations of paragraph 2 of the Complaint and therefore denies those allegations.

3. Ranbaxy lacks sufficient information to respond to the allegations of paragraph 3 of the Complaint and therefore denies those allegations.

4. Ranbaxy lacks sufficient information to respond to the allegations of paragraph 4 of the Complaint and therefore denies those allegations.

5. Ranbaxy lacks sufficient information to respond to the allegations of paragraph 5 of the Complaint and therefore denies those allegations.

6. Ranbaxy lacks sufficient information to respond to the allegations of paragraph 6 of the Complaint and therefore denies those allegations.

7. Ranbaxy lacks sufficient information to respond to the allegations of paragraph 7 of the Complaint and therefore denies those allegations.

8. Ranbaxy admits that Ranbaxy Inc. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 600 College Road East, Princeton, New Jersey. Ranbaxy denies any and all remaining allegations in paragraph 8 of the Complaint.

9. Ranbaxy admits that Ranbaxy Laboratories Limited is a corporation organized and existing under the laws of India, having its principal place of business at Plot 90, Sector 32, Gurgaon (Haryana), India. Ranbaxy denies any and all remaining allegations in paragraph 9 of the Complaint.

10. Ranbaxy lacks sufficient information to respond to the allegations of paragraph 10 of the Complaint and therefore denies those allegations.

11. Ranbaxy lacks sufficient information to respond to the allegations of paragraph 11 of the Complaint and therefore denies those allegations.

12. Ranbaxy lacks sufficient information to respond to the allegations of paragraph 12 of the Complaint and therefore denies those allegations.

13. Ranbaxy lacks sufficient information to respond to the allegations of paragraph 13 of the Complaint and therefore denies those allegations.

14. Ranbaxy lacks sufficient information to respond to the allegations of paragraph 14 of the Complaint and therefore denies those allegations.

Nature of the Action[1]

15. Ranbaxy admits that this action concerns U.S. Patent No. 4,661,491 ("the '491 patent"), but not with respect to Ranbaxy. Ranbaxy admits that this action concerns U.S. Patent No. 6,149,940 ("the '940 patent") with respect to Ranbaxy, and that Exhibits A and B of the Complaint purport to be a copies of the '491 and '940 patents, respectively. Ranbaxy also admits that this action arises under the Patent Laws of the United States, Title 35. Ranbaxy denies any and all remaining allegations in paragraph 15 of the Complaint.

Jurisdiction and Venue

16. Paragraph 16 of the Complaint states legal conclusions to which no response is required. To the extent a response is required, Ranbaxy admits that this Court has jurisdiction over the subject matter of this action with respect to Ranbaxy pursuant to 28 U.S.C. §§ 1331 and 1338(a). Ranbaxy denies any and all remaining allegations set forth in paragraph 16 of the Complaint.

17. Paragraph 17 of the Complaint states legal conclusions to which no response is required. To the extent a response is required, Ranbaxy admits that it is subject to personal jurisdiction in this judicial district for this action. Ranbaxy denies any and all remaining allegations in paragraph 17 of the Complaint.

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[1] For the Court's convenience, Ranbaxy has incorporated the "Headings" that appear in Sanofi's Complaint. It should be understood, however, that Ranbaxy does not necessarily agree with the characterizations of such Headings, and does not waive any right to object to those characterizations.

18-22. Paragraphs 18-22 of the Complaint do not pertain to Ranbaxy. Thus, Ranbaxy provides no response. Additionally, Ranbaxy is without information sufficient to form a belief as to the truth of the allegations in paragraphs 18-22, and therefore denies those allegations.

23. Paragraph 23 of the Complaint states legal conclusions to which no response is required. To the extent a response is required, Ranbaxy admits that Ranbaxy Inc. is a Delaware corporation and is subject to personal jurisdiction in this judicial district for this action. Ranbaxy denies any and all remaining allegations in paragraph 23 of the Complaint.

24. Paragraph 24 of the Complaint states legal conclusions to which no response is required. To the extent a response is required, Ranbaxy admits that Ranbaxy Laboratories Limited is subject to personal jurisdiction in this judicial district for this action. Ranbaxy denies any and all remaining allegations in paragraph 24 of the Complaint.

25-29. Paragraphs 25-29 of the Complaint do not pertain to Ranbaxy. Thus, Ranbaxy provides no response. Additionally, Ranbaxy is without information sufficient to form a belief as to the truth of the allegations in paragraphs 25-29, and therefore denies those allegations.

30. Paragraph 30 of the Complaint states legal conclusions to which no response is required. To the extent a response is required, Ranbaxy admits that, with respect to Ranbaxy, venue is proper in this judicial district for this action.

The Patents

31. Ranbaxy admits that the '491 patent states on its face that it is entitled, "Alfuzosine Compositions and Use," and was issued on April 28, 1987. Ranbaxy also admits that the Orange Book lists Sanofi-Aventis U.S. as the applicant for New Drug Application No. 21-287 on Uroxatral® brand alfuzosin hydrochloride extended release tablets, and that the '491 patent is listed in the Orange Book for Uroxatral.® Ranbaxy lacks sufficient information

regarding the remaining allegations in paragraph 31 of the Complaint, and therefore denies those allegations.

32. Ranbaxy admits that the '940 patent states on its face that it is entitled, "Tablet with Controlled Release of Alfuzosine Chlorhydrate," and issued on November 21, 2000. Ranbaxy also admits that the '940 patent is listed in the Orange Book for Uroxatral®. Ranbaxy lacks sufficient information regarding the remaining allegations in paragraph 32 of the Complaint, and therefore denies those allegations.

Acts Giving Rise to this Action

Counts I – VI Infringement of the '491 Patent and the '940 Patent by Actavis, Par, Aurobindo Ltd. Aurobindo, Inc., and Mylan

33-70. The allegations contained in paragraphs 33-70 of the Complaint do not pertain to Ranbaxy. Thus, Ranbaxy provides no response. Additionally, Ranbaxy is without information sufficient to form a belief as to the truth of the allegations contained in paragraphs 33-70, and on that basis denies them.

Count VII – Infringement of the '940 Patent by Defendants Ranbaxy Ltd. and Ranbaxy Inc.

71. Ranbaxy admits that it submitted Abbreviated New Drug Application ("ANDA") No. 79-006 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, seeking approval to engage in the commercial manufacture, use or sale of a generic version of Sanofi's Uroxatral® brand alfuzosin hydrochloride extended release 10 mg tablets prior to the expiration of the '940 patent. Ranbaxy denies any and all remaining allegations in paragraph 71 of the Complaint.

72. Ranbaxy admits that ANDA 79-006 certifies under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that no valid claims of the '940 patent will be infringed by

the manufacture, use, sale or offer to sell of Ranbaxy's ANDA product, and that Sanofi received written notification of ANDA 79-006 on August 14, 2007. Ranbaxy denies any and all remaining allegations in paragraph 72 of the Complaint.

73. Ranbaxy denies the allegations in paragraph 73 of the Complaint.

74. Ranbaxy denies the allegations in paragraph 74 of the Complaint.

75. Ranbaxy denies the allegations in paragraph 75 of the Complaint.

76. Ranbaxy denies the allegations in paragraph 76 of the Complaint.

77. Ranbaxy denies the allegations in paragraph 77 of the Complaint.

Counts VIII – XII Infringement of the '940 Patent by Sun Inc., Sun Ltd., Teva, Torrent Ltd., and Torrent, Inc., and Infringement of the '491 Patent by Teva, Torrent Ltd, and Torrent Inc.

78-108. The allegations contained in paragraphs 78-108 of the Complaint do not pertain to Ranbaxy. Thus, Ranbaxy provides no response. Additionally, Ranbaxy is without information sufficient to form a belief as to the truth of the allegations contained in paragraphs 78-108, and on that basis denies them.

AFFIRMATIVE DEFENSES

Ranbaxy sets forth the following affirmative and other defenses. Ranbaxy does not intend hereby to assume the burden of proof with respect to those matters that, pursuant to law, Sanofi bears the burden.

First Affirmative Defense

(Noninfringement of the '940 patent)

109. Ranbaxy does not infringe, through direct, contributory, or induced infringement, any valid and enforceable claim of the '940 patent.

Second Affirmative Defense

(Invalidity of the '940 patent)

110. The '940 patent is invalid for failure to satisfy the provisions of one or more of Sections 101, 102, 103 and/or 112 of Title 35 of the United States Code.

Third Affirmative Defense

(Failure to State a Claim)

111. Count VII of the Complaint fails to state a claim for relief upon which relief can be granted against Ranbaxy.

RANBAXY'S COUNTERCLAIMS

Defendants/Counterclaimants Ranbaxy Laboratories Limited and Ranbaxy Inc. (collectively, "Ranbaxy") bring the following Counterclaims against Sanofi-Aventis and Sanofi-Aventis U.S. LLC (collectively, "Sanofi"), for declaratory judgment that U.S. Patent No. 6,149,940 (the "'940 patent") is invalid and/or not infringed by the alfuzosin hydrochloride product in Ranbaxy's Abbreviated New Drug Application No. 79-006 (Ranbaxy's "ANDA product").

PARTIES, JURISDICTION AND VENUE

112. These counterclaims seek a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202, and the Patent Laws of the United States.

113. Counterclaimant Ranbaxy Laboratories Limited is a corporation organized and existing under the laws of India, having its principal place of business at Plot 90, Sector 32, Gurgaon (Haryana), India. Counterclaimant Ranbaxy Inc. is a corporation organized and

existing under the laws of Delaware, having its principal place of business at 600 College Road East, Princeton, New Jersey.

114. On information and belief, Counterdefendant Sanofi-Aventis is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.

115. On information and belief, Counterdefendant Sanofi-Aventis U.S. LLC is a limited liability company organized and existing under the laws of Delaware, with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey, 08807.

116. This is an action based upon an actual controversy between Ranbaxy and Sanofi concerning the invalidity and/or noninfringement of the '940 patent, and Ranbaxy's right to continue to seek approval of Ranbaxy's ANDA product, and upon approval by the FDA, to manufacture, import, use, market, sell and offer to sell its ANDA product in the United States.

117. This Court has jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202 and 35 U.S.C. § 271(e)(2).

118. Venue is proper under 28 U.S.C. §§ 1391 and 1400, and by Sanofi's choice of forum.

119. Ranbaxy has submitted, and is continuing to seek FDA approval of, an ANDA directed to a product containing alfuzosin hydrochloride, a generic version of Sanofi's Uroxatral® product. Ranbaxy's ANDA seeks approval for Ranbaxy to engage in the commercial manufacture, use and sale of a product containing alfuzosin hydrochloride, which Sanofi alleges infringes the '940 patent.

120. Ranbaxy has undertaken substantial efforts in developing and seeking approval for its ANDA product.

121. Sanofi has sued Ranbaxy for alleged infringement of the '940 patent based on Ranbaxy's ANDA product.

122. Ranbaxy's ANDA product does not infringe any valid and enforceable claims of the '940 patent. The claims of the '940 patent are invalid for failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and/or 112.

123. In view of the foregoing, a conflict of asserted rights has arisen between Ranbaxy and Sanofi with respect to the infringement, validity and/or enforceability of the relevant claims of the '940 patent, and as to Ranbaxy's right to obtain FDA approval to engage in the commercial manufacture, importation, use, offer for sale, and sale of its ANDA product. An actual controversy exists between Ranbaxy and Sanofi.

FIRST COUNTERCLAIM — DECLARATION OF NONINFRINGEMENT OF THE '940 PATENT

124. Ranbaxy repeats and realleges paragraphs 112-23 as if set forth specifically herein.

125. Ranbaxy does not infringe any valid and enforceable claim of the '940 patent.

SECOND COUNTERCLAIM — DECLARATION OF INVALIDITY OF THE '940 PATENT

126. Ranbaxy repeats and realleges paragraphs 112-23 as if set forth specifically herein.

127. The '940 patent is invalid for failure to satisfy the provisions of one or more of Sections 101, 102, 103 and/or 112 of Title 35 of the United States Code.

DEMAND FOR JUDGMENT

WHEREFORE, Ranbaxy prays for the following relief:

A. That all claims against Ranbaxy be dismissed with prejudice and that all relief requested by Sanofi be denied;

B. That a judgment be entered declaring that Ranbaxy has not, and does not, infringe any valid claim of U.S. Patent No. 6,149,940, that Ranbaxy has a lawful right to obtain FDA approval of its ANDA product, and further that Ranbaxy has a lawful right to manufacture, import, market, use, sell and/or offer to sell its ANDA product once approved by FDA;

C. That a judgment be entered declaring that the claims of U.S. Patent No. 6,149,940 are invalid;

D. That Sanofi and its agents, representatives, attorneys and those persons in active concert or participation with them who received actual notice hereof, be preliminarily and permanently enjoined from threatening or initiating infringement litigation against Ranbaxy or any of its customers, dealers or suppliers, or any prospective sellers, dealers, distributors or customers of Ranbaxy, or charging any of them either orally or in writing with infringement of U.S. Patent No. 6,149,940;

E. That a judgment be entered declaring this action is an exceptional case within the meaning of 35 U.S.C. § 285 and that Ranbaxy is entitled to recover its reasonable attorneys' fees upon prevailing in this action;

F. That Ranbaxy be awarded costs, attorneys' fees and other relief, both legal and equitable, to which they may be justly entitled; and

G. That Ranbaxy be awarded such other and further relief as is just and proper.

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Dated: January 7, 2008

CERTIFICATE OF SERVICE

I hereby certify that on January 7, 2008, I electronically filed the foregoing with the Clerk of Court using CM/ECF which will send notification of such filing(s) to the following and which has also been served as noted:

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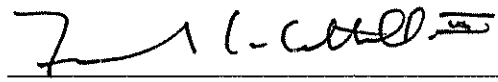

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